AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listing, of claims in the application:

Listing of Claims:

Claims 1-34 (canceled)

Claim 35. (currently amended) A method of purifying rhUG comprising the steps of:

a. providing a bacterial cell paste comprising bacterial cells capable of overexpressing rhUG;

b. lysing the bacterial cell paste and pelleting the debris to form a supernatant;

c. filtering the supernatant formed in step b through a first nominal molecular weight cut off ~~(NMWCO)~~ membrane to form a first permeate;

d. concentrating the first permeate formed in step c by the use of a second nominal molecular weight cut off ~~NMWCO~~ membrane;

e. loading the concentrated permeate formed in step d onto an anion exchange column to form a first eluate;

f. concentrating the first eluate formed in step e by the use of a third nominal molecular weight cut off ~~NMWCO~~ membrane to form a second concentrate;

g. loading the second concentrate formed in step f onto a hydroxyapatite ~~Hydroxyapatite~~ ~~(HA)~~ column to form a second eluate;

h. separating host-derived proteins from the rhUG in the second eluate formed in step g to provide purified rhUG; and

i. recovering the purified rhUG formed in step h.

Claim 36. (currently amended) The method of claim 35, wherein the rhUG expressed in the bacterial cells is ~~a synthetic gene~~ a polypeptide comprising the amino acid sequence of Seq. ID No. 11 ~~selected from the group consisting of Seq. ID Nos. 1, 2, 3 and 4~~.

Claim 37. (original) The method of claim 35, wherein lysing comprises shearing.

Claim 38. (original) The method of claim 35, wherein between step b and step c, cell debris is removed by centrifugation.

Claim 39. (currently amended) The method of claim 35, wherein the membrane of step b is about a 30K to 100K nominal molecular weight cut off ~~NMWCO~~ membrane.

Claim 40. (currently amended) The method of claim 39, wherein the filtering of step c comprises the use of a tangential flow filtration ~~(TFF)~~ system.

Claim 41. (currently amended) The method of claim 35, wherein the membrane of step d is about a 5K nominal molecular weight cut off ~~NMWCO~~ membrane.

Claim 42. (canceled)

Claim 43. (currently amended) The method of claim 41, wherein the host-derived proteins of step h are separated with a chelating fast flow ~~Chelating Fast Flow (CSFF)~~ resin column.

Claim 44. (currently amended) The method of claim 43, wherein the ~~CSFF~~ chelating fast flow resin column comprises copper.

Claim 45. (currently amended) The method of claim 44, wherein after step h a positively charged membrane is placed downstream of the ~~CSFF~~ chelating fast flow resin column forming a pass through substantially free of host derived proteins.

Claim 46. (previously presented) The method of claim 45, wherein the positively charged membrane is a filtration membrane.

Claim 47. (currently amended) The method of claim 35, wherein the second eluate is diafiltered through about a 30K nominal molecular weight cut off ~~NMWCO~~ membrane.

Claim 48. (original) The method of claim 35, wherein the rhUG recovered in step i is substantially free of aggregates.

Claim 49. (currently amended) A method of purifying rhUG comprising the steps of:

a. providing bacterial cells capable of overexpressing rhUG;

b. lysing the bacterial cells and pelleting the debris to form a supernatant liquid;

c. filtering the liquid through a nominal molecular weight cut off ~~(NMWCO)~~ membrane;

d. loading the liquid onto an ion exchange column;

e. separating host-derived proteins from the rhUG to provide purified rhUG; and

f. recovering the purified rhUG

wherein the level of endotoxin in said rhUG is less than 5 EU/mg.

Claim 50. (currently amended) The method of claim 49, wherein the rhUG expressed in the bacterial cells is ~~a synthetic gene~~ a polypeptide comprising the amino acid sequence of Seq. ID No. 11 ~~selected from the group consisting of Seq. ID Nos. 1-4~~.

Claim 51. (currently amended) The method of claim 49, wherein the filtering of step c comprises the use of a tangential flow filtration ~~(TFF)~~ system.

Claim 52. (canceled)

Claim 53. (currently amended) The method of claim 49, wherein the host-derived proteins of step e are separated with a ~~Chelating Fast Flow (CSFF)~~ chelating fast flow resin column.

Claim 54. (currently amended) The method of claim 49, wherein the rhUG recovered in step ~~i~~ f is substantially free of aggregates.

Claim 55. (currently amended) A method of producing a pharmaceutical grade rhUG drug substance comprising the steps of:

a. providing a bacterial expression system capable of expressing rhUG;

b. inoculating a fermenter with an inoculum comprising the bacterial expression system to form a fermentation culture;

c. adding an induction agent to the fermentation culture to induce the expression of rhUG by the bacterial expression system;

d. harvesting the rhUG expressed in step c; and

e. purifying the rhUG harvested in step d, ~~wherein the purifying step comprises the use of at least one filtration step and~~ by filtering the rhUG and passing the filtrate through at least one exchange column

wherein the rhUG produced is of pharmaceutical grade and wherein the level of endotoxin in said rhUG is less than 5 EU/mg.

Claim 56-73. (canceled)

Claim 74. (currently amended) The method of claim 35 further comprising steps for determining the purity of recombinant human uteroglobin ~~comprising,~~ comprising:

(a) taking samples ~~of intermediates~~ at each step within the process of claim 35 and

(b) analyzing ~~the process intermediates~~ said samples to determine purity (i) relative to unpurified recombinant human uteroglobin or

~~(c) analyzing the process intermediates to determine purity~~ (ii) relative to purified recombinant human uteroglobin taken from a step of claim 35 which precedes the step within the process of claim 35 from which said samples ~~of intermediates~~ were taken.

Claim 75. (original) The method of claim 74, wherein process intermediates are analyzed by SDS-PAGE.

Claim 76. (original) The method of claim 74, wherein process intermediates are analyzed by rhUG ELISA.

Claim 77. (original) The method of claim 74, wherein process intermediates are analyzed by LAL.

Claim 78. (original) The method of claim 74, wherein process intermediates are analyzed for protein content.

Claim 79-100. (canceled)

Claim 101. (previously presented) The method of claim 35 wherein said purified rhUG is of pharmaceutical grade.

Claim 102. (previously presented) The method of claim 49 wherein said purified rhUG is of pharmaceutical grade.

Claim 103. (previously presented) The method of claim 74 wherein said purified rhUG is of pharmaceutical grade.